

In the Claims:

1-43 (Cancel)

44. (Amended) A method for monitoring malignancy in a test subject comprising:

- a. obtaining a biological specimen from a test subject, said specimen comprising a mixed cell population suspected of containing intact malignant cells and further comprising:
 - i. cell fragments derived from malignant cells, or
 - ii. cellular debris derived from malignant cells;
- b. preparing a magnetically-labeled sample with magnetically-labeled said intact malignant cells, cell fragments and said cellular debris wherein said biological sample is mixed with magnetic particles coupled to a first biospecific ligand which reacts specifically with said intact malignant cells, and said cell fragments or said cellular debris, to the substantial exclusion of other specimen components when said sample is exposed to an externally-applied magnetic field;
- c. contacting said magnetically-labeled sample having magnetically-labeled said intact malignant cells, cell fragments and said cellular debris with at least one additional biospecific ligand forming a specific binding pair with a receptor on which specifically labels said intact malignant cells, and said cell fragments or said cellular debris, to the substantial exclusion of other specimen components;
- d. analyzing said labeled malignant cells, and said labeled cell fragments or said labeled cellular debris over time, a change in the presence of said labeled malignant cells, said labeled cell fragments, and said labeled cellular debris indicating the presence a change of malignancy.

45. The method of Claim 44, wherein said biological specimen is blood.

46. The method of Claim 45, wherein after said biological specimen obtained, it is contacted with an agent capable of stabilizing said biological specimen.

47. The method of Claim 44, wherein said magnetic particles are colloidal.

48. The method of Claim 44, wherein after the step of preparing said magnetically-labeled sample, said sample is subjected to a high gradient magnetic field to

produce a separated magnetically-labeled fraction which is enriched for said intact malignant cells, and said cell fragments or said cellular debris.

49. The method of Claim 44, wherein said analysis is selected from the group consisting of: multiparameter flow cytometry, immunofluorescent microscopy, laser scanning cytometry, bright field base image analysis, capillary volumetry, spectral imaging analysis, manual cell analysis, and automated cell analysis.
50. The method of Claim 44, wherein said analysis further comprises classifying cell fragments or said cellular debris based on their origin as caused by apoptosis or necrosis.
51. The method of Claim 50, wherein analysis further comprises classifying cell fragments or said cellular debris based on their origin as caused by mechanical damage, drug-induced damage, or immunological damage.
52. The method of Claim 50, wherein said classification is based on at least one of the group consisting of: morphologic analysis and epitopic analysis.

53. (Amended) A method for monitoring malignancy in a test subject comprising:

- a. obtaining a biological specimen from a test subject, said specimen comprising a mixed cell population suspected of containing intact malignant cells and clusters of malignant cells;
- b. preparing a magnetically-labeled sample with magnetically-labeled said intact malignant cells and said clusters of malignant cells wherein said biological sample is mixed with magnetic particles coupled to a first biospecific ligand which reacts specifically with said intact malignant cells and said clusters of malignant cells, to the substantial exclusion of other specimen components when said sample is exposed to an externally-applied magnetic field;
- c. contacting said magnetically-labeled sample having magnetically-labeled said intact malignant cells, cell fragments and said cellular debris with at least one additional biospecific ligand forming a specific binding pair with a receptor on which specifically labels said intact malignant cells and said

clusters of malignant cells, to the substantial exclusion of other specimen components;

- d. analyzing said labeled malignant cells and said labeled clusters of malignant cells over time, a change in the presence of said labeled malignant cells and said labeled clusters of malignant cells indicating the presence a change of malignancy.

54. The method of Claim 53, wherein said biological specimen is blood.

55. The method of Claim 54, wherein after said biological specimen obtained, it is contacted with an agent capable of stabilizing said biological specimen.

56. The method of Claim 53, wherein said magnetic particles are colloidal.

57. The method of Claim 53, wherein after the step of preparing said magnetically-labeled sample, said sample is subjected to a high gradient magnetic field to produce a separated magnetically-labeled fraction which is enriched for said intact malignant cells and said clusters of malignant cells.

58. The method of Claim 53, wherein said analysis is selected from the group consisting of: multiparameter flow cytometry, immunofluorescent microscopy, laser scanning cytometry, bright field base image analysis, capillary volumetry, spectral imaging analysis, manual cell analysis, and automated cell analysis.

59. A kit for assaying a biological specimen for the presence of malignant cells, and cell fragments derived from malignant cells or cellular debris derived from malignant cells, comprising:

- a. coated magnetic nanoparticles comprising:
 - i. a magnetic core material,
 - ii. a protein base coating material, and
 - iii. an antibody that binds specifically to a first characteristic determinant of said malignant cell, and said cell fragments or said cellular debris, wherein said antibody is coupled to said base coating material;

- b. at least one antibody having binding specificity for a second characteristic determinant of said malignant cell, and said cell fragments or said cellular debris;
- c. an agent capable of staining further features of said malignant cells, and said cell fragments or said cellular debris.

60. The kit of Claim 59, further comprising a panel of antibodies each specific for a different characteristic determinant.

61. The kit of Claim 59, further comprising a specific agent capable of labeling non-target entities.